K082107

DigiMed

SEP 26 2008

5 510(k) Summary

5.1 Company and Correspondent Making the Submission:

Date Prepared:	June 16, 2008
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E-mail:	digi-med@hanmail.net
Contact:	Youngbae Kwon, Managing Director

5.2 US Agent for FDA Contact:

Name:	Shin Kuk Yoo
Company:	LSK BioPartners, Inc.
Address:	215 S. State St. STE100B Salt Lake City, Utah 84111
Tel:	801-303-7440 (Ext. 202)
Fax:	801-303-7455
Email:	skyone@LSKBioPartners.com

5.3 Device Information:

Proprietary-Trade Name:	Portable X-Ray System (Models: DIOX-602, PROX)
Classification Name:	Extraoral Source X-Ray System: EHD, Class II per regulation 21CFR 872.1800
Common/Usual Name:	Portable X-Ray System

5.4 Predicate Devices:

Manufacturer:	GENORAY Co., Ltd.
Device:	Portable X-Ray System (Model: PORT-X II)
Classification:	Extraoral Source x-Ray System: EHD, Class II per regulation 21CFR 872.1800
510(k) Number:	K063121 (Decision Date: Jan. 11, 2007)

5.5 Indications for Use (Intended Use):

The Portable X-ray System (Model: DIOX-602, PROX) is intended to be used by trained dentists and dental technicians as extraoral x-ray source for producing diagnostic x-ray images using intraoral image receptors. Its use is intended for both adult and pediatric subjects.

5.6 Description of Device

The Portable X-ray System (Model: DIOX-602, PROX) is portable dental X-ray system that operates on 24VDC supplied by a rechargeable Li-Polymer battery pack. The X-ray controls and power source are assembled into a single hand-held enclosure. The package includes battery charger.

The Portable X-ray System generates and controls X-ray in order to diagnose of tooth and jaw. It is composed of X-ray generator, controller and beam limiting device. Operating principle is that X-ray generated by high voltage electricity into X-ray tube, which penetrates tooth and jaw, and makes X-ray images on receptor (chemical film or digital sensor).

The Portable X-ray System (Model: DIOX-602, PROX) is a diagnostic x-ray system, which is intended to be used by trained dentists and dental technicians as an extra-oral x-ray source for producing diagnostic x-ray images using intra-oral image receptors.

Its use is intended for both adult and pediatric subjects. This device includes a high frequency inverter that changes direct current to alternating current, X-ray tube, electrical protective devices, and other elements. The portable X-ray system (Model: DIOX-602, PROX) provides with sharp and clear images and keeps patients and dentists away from radiation using small dose of radiation.

5.7 Safety and Effectiveness, Comparison to Predicate Device:

The result of bench testing and clinical evaluation indicates that the subject device is as safe and effective as the predicate devices.

5.8 Safety, EMC and Performance Data:

The portable x-ray system, DIOX-602 and PROX, will comply with applicable requirements of the Underwriters Laboratories Standard for Safety-UL/IEC 60601-1, IEC 60601-1-3, IEC 60601-2-7, IEC 60601-2-28 and IEC 60601-2-32. All required documents and reports will be submitted to the appropriate oversight agency to establish compliance with the applicable requirements.

EMS testing was conducted by EMC Compliance Co., Ltd. for DIOX-602 and SGS Testing Korea Co., Ltd. for PROX in accordance with Standard EN/IEC 60601-1-2. All test results were satisfactory.

5.9 Substantial Equivalence Chart

Company	GENORAY Co.	DIGIMED Corp.	
Model	PORT-X II	DIOX-602	PROX
510(k) No	K063121	New	
Energy source	Rechargeable 22.2V DC Lithium Polymer battery pack	Rechargeable 24V, DC Lithium Polymer Battery pack	
Expose time	0.01-2.0 seconds 0.01 increments	0.01-1.6 seconds, 0.01 increments	
Time accuracy	±(10%+1ms)	±(10%+1ms)	
mA	2mA fixed	2mA fixed	
kVp	60kV fixed	60kV fixed	
Wave form	Constant Potential (DC)	Constant Potential (DC)	
Safety, EMC and performance	IEC 60601-1, IEC 60601-2-7 IEC 60601-2-28, IEC 60601-2-32	IEC 60601-1, IEC 60601-2-7, IEC 60601-2-28, IEC 60601-2-32	
Source to skin distance	20cm	20cm	
Cone diameter	7Cm	6 .5 Cm	6 Cm
User Interface	Exposure time: up, down. Selection buttons of parts of teeth, adult and child, film and sensor with display.	Exposure time: up, down. Two buttons for modes and selection of parts of teeth, adult and child, film and sensor with display.	Exposure time: up, down. Selection buttons of parts of teeth, adult and child, film and sensor with display.
Exposure switch	Control panel and remote controller	Control panel and remote controller	
Tube head mounting	Yes	Yes	
Intended use	Intended to use by trained dentists and dental technicians as an extra-oral x-ray source for producing diagnostic x-ray images using intra-oral image receptors or film. It is intended to use for both adult and pediatric subjects.		

5.10 Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided the above comparison table, the DIGIMED Corporation concludes that the portable X-ray System (Model: DIOX-602, PROX) is safe and effective and substantially equivalent to the predicate device as described above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 6 2008

DIGIMED Corporation
% Mr. Shin Kuk Yoo
Business Development Manager
LSK BioPartners, Inc.
215 S. State Street, STE 100B
SALT LAKE CITY UT 84111

Re: K082167
Trade/Device Name: Portable x-ray system (Models: DIOX-602, PROX)
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: EHD
Dated: July 29, 2008
Received: July 31, 2008

Dear Mr. Yoo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082167

Device Name: Portable x-ray system (Models: DIOX-602, PROX)

Indications for Use:

The Portable X-ray System (Model: DIOX-602, PROX) is intended to be used by trained dentists and dental technicians as extraoral x-ray source for producing diagnostic x-ray images using intraoral image receptors. Its use is intended for both adult and pediatric subjects.

Prescription Use ___V___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number _____